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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,679

09/12/2005

Charles Henry Horn

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EXAMINER

HENKEL, DANIELLE B

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,679	HORN, CHARLES HENRY	
	Examiner	Art Unit	
	DANIELLE HENKEL	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office action on the 10/521679 application filed on 9/12/2005.
2. Claims 1-32 were cancelled in a preliminary amendment on 9/25/2005, claims 33-55 are pending and have been fully considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 44 recites the limitation "the septum" in line 2. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 46 recites the limitation "the septum" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 33-37, 44-47, 48-49, 52, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by KERTZ (WO 90/15527).

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- a. With respect to claim 33, KERTZ teaches an apparatus for culturing a living organic material comprising an anaerobic proliferation chamber (cellule) (Page 15, Paragraph 2) containing a growth medium (Page 35, Paragraph 3 - Page 36, Paragraph 1), and inoculation chamber (inner container) containing an inoculum (Page 29, Paragraph 3), and an openable separator (material of inner container) that separates the proliferation chamber from the inoculation chamber, wherein opening of the separator allows inoculation of the growth medium with the inoculum (Page 11, Paragraph 2- Page 12, Paragraph 1). As the inoculum chamber is sterile and closed from contaminants (Page 20, Paragraph 2), the inoculum will be stable and viable beyond those in conventional culture containers (Page 31, Paragraph 3).
- b. With respect to claim 34, KERTZ teaches the apparatus is totally enclosed (Page 7, Paragraph 2) and hermetically sealed (heat sealed and anaerobic chamber) (Page 8, Paragraph 2, and Page 15, Paragraph 2).
- c. With respect to claim 35, KERTZ teaches the separator (material of inner container) and the inside of the proliferation chamber are sterile (Page 20, Paragraph 2).
- d. With respect to claim 36, KERTZ teaches the inoculation chamber is anaerobic (not gas permeable, closed from environment) (Page 8, Paragraph 1 and Page 20, Paragraph 2).
- e. With respect to claim 37, KERTZ teaches an opener (flat edge) for opening the separator without compromising the anaerobic quality of the inside of the

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chambers (Page 11, Paragraph 2 – Page 12, Paragraph 3 and Page 4, Paragraph 3).

- f. With respect to claim 44, the term septum has no antecedent basis in claim 33 from which it depends (see above 112 rejections), therefore the examiner assumes claim 44 intended to refer to the openable separator as in line 3 of claim 33. KERTZ teaches the inoculation chamber is flexible and compressible after the separator has been opened (Page 11, Paragraph 2 – Page 12, Paragraph 1).
- g. With respect to claim 45, KERTZ teaches an urging function (pressing) that urges the inoculum into the proliferation chamber after the separator has been opened (Page 11, Paragraph 2 - Page 12, Paragraph 1).
- h. With respect to claim 46, KERTZ teaches a pressure difference between chambers (pressure on inner container) causes the inoculum to flow into the proliferation chamber after the separator has been opened (Page 11, Paragraph 2).
- i. With respect to claim 47, KERTZ teaches the pressure difference is created during the anaerobic cultivation of the cells, tissue culture, or microorganisms in the inoculation chamber (Page 11, Paragraph 2- Page 12, Paragraph 1).
- j. With respect to claim 48, KERTZ teaches a port (tube) for connecting to a dosing or application means (Page 10, Paragraph 3).
- k. With respect to claim 49, KERTZ teaches the proliferation chamber comprises a flexible (expandable) bag-type container (Page 8, Paragraph 2 and Figure 4).

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- l. With respect to claim 52, KERTZ teaches a method comprising disposing an inoculum in an inoculation chamber (inner container) (Page 29, Paragraph 3) and disposing a growth medium for the inoculum in an anaerobic proliferation chamber (Page 29, Paragraph 3 and Page 15, Paragraph 2) which is separated from the inoculation chamber by an openable separator (Page 11, Paragraph 2- Page 12, Paragraph 1), opening the separator to inoculate the growth medium (Page 30, Paragraph 1), allowing the cells, tissue cultures, and or microorganisms to proliferate under anaerobic conditions in the proliferation chamber to form a proliferated culture (Page 30, Paragraph 2- Page 31, Paragraph 1), and dispensing the proliferated culture from the proliferation chamber (Page 31, Paragraph 1).
- m. With respect to claim 54, KERTZ teaches controlling proliferation conditions of the inoculated growth medium (Page 42, Paragraph 5 - Page 43, Paragraph 1).
- n. With respect to claim 55, KERTZ teaches a unitary (Figure 1), disposable (Page 16, Paragraph 2), and portable (Page 9, Paragraph 2) apparatus comprising an anaerobic proliferation chamber (cellule) (Page 15, Paragraph 2) containing a growth medium (Page 35, Paragraph 3 - Page 36, Paragraph 1), and inoculation chamber (inner container) containing an inoculum (Page 29, Paragraph 3), and a means for separating the proliferation and inoculation chambers (openable separator), the separating means being openable to connect the insides of the chambers to each other to inoculate the growth medium with the inoculum (Page 11, Paragraph 2- Page 12, Paragraph 1) wherein the inoculum and growth

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medium are stored and transported separated from each other in the apparatus until such time as a proliferated culture is to be applied (Page 29, Paragraph 3 – Page 30, Paragraph 2 and Page 33, Paragraph 3–Page 34, Paragraph 1), whereupon the growth medium is inoculated and proliferation allowed to take place, whereafter the proliferated culture is dispensed from the apparatus (Page 30, Paragraph 2 – Page 31, Paragraph 2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 47, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over KERTZ (WO 90/15527).

- a. With respect to claim 50, KERTZ does not explicitly disclose the proliferation chamber comprises a carboy-type container. However, it would be a matter of

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obvious design choice of one having ordinary skill in the art at the time that the invention was made, since a flexible bag and a carboy are both well known culture containers.

- b. With respect to claim 53, KERTZ teaches the inoculation chamber is anaerobic (not gas permeable, closed from environment) (Page 8, Paragraph 1 and Page 20, Paragraph 2), and the steps of inoculating (Page 11, Paragraph 2 – Page 12, Paragraph 3 and Page 4, Paragraph 3), opening (Page 11, Paragraph 2 – Page 12, Paragraph 3 and Page 4, Paragraph 3), and proliferation occur anaerobically (Page 15, Paragraph 2). KERTZ does not explicitly disclose the steps of disposing occur anaerobically. However, KERTZ does teach that materials can be disposed in the chambers after they are sealed through the use of a tube (Page 10, Paragraph 3) and that the culture can be preformed anaerobically (Page 15, Paragraph 2). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to perform all steps of preparing an anaerobic culture vessel anaerobically.

11. Claims 38-43, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over KERTZ (WO 90/15527) in view of BITTINGS (US 4358539).

- a. With respect to claim 38, KERTZ does not explicitly disclose the chambers are connected by a passage comprising the separator. However, BITTINGS teaches a subculture device for transferring inoculum in which a passage (neck of culture bottle) is provided between a culture chamber (culture media well) and inoculum

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container (culture bottle) comprising the separator (septum) (Column 2, line 55-Column 3, line 32, Figure 1). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the culture apparatus of KERTZ to include the inoculum transfer including a passage comprising the separator as taught by BITTINGS because it allows for a minimum of handling, thus reducing contamination as well as eliminates the need for a separate transfer syringe and needle (Column 3, lines 40-55).

- b. With respect to claim 39, BITTINGS teaches the separator comprises a septum because it is standard on a culture bottle containing inoculum (Column 1, lines 36-44).
- c. With respect to claim 40, BITTINGS teaches the opener comprises a spike (needle) for piercing the septum because it is common for transferring inoculum to media through the septum of a standard culture bottle (Column 1, lines 36-44).
- d. With respect to claim 41, BITTINGS teaches the inoculation chamber comprises a mouth (neck of bottle) connected to one end of the passage (Column 3, lines 19-32). BITTINGS does not explicitly disclose the inoculation chamber comprises a vial-type container, however, BITTINGS does disclose the chamber is a standard culture bottle. It would be obvious to one of ordinary skill in the art at the time of the invention to use a vial-type container as the inoculation chamber because the use of vial-type containers for holding inoculum where well known in the art.

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- e. With respect to claim 42, BITTINGS teaches the septum covers the mouth (Column 3, lines 19-32).
- f. With respect to claim 43, BITTINGS teaches the spike is mounted in the passage and directed at the septum (Figure 1), and wherein the mouth of the inoculation chamber is connected to the passage by an advancer (a person) that advances the inoculation chamber towards the spike thereby allowing the spike to pierce the septum (Column 3, lines 19-32).
- g. With respect to claim 51, KERTZ does not explicitly disclose an incubator for controlling the proliferation conditions. However, BITTINGS teaches incubating the apparatus (Column 1, lines 45-50). At the time of the invention it would have been obvious to modify the apparatus of KERTZ to include an incubator as taught in BITTINGS because incubators are well known in the art to provide the proper environment for the proliferation of cells and organisms.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/DANIELLE HENKEL/
Examiner, Art Unit 1797